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| 10/500,861 | 10/20/2004 | Yuko Matsumura | P25617 | 5143 |

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| EXAMINER | |
|---|---|
| SZPIRA, JULIE ANN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3731 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 02/18/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/500,861 | MATSUMURA ET AL. | |
| | Examiner | Art Unit | |
| | JULIE A. SZPIRA | 3731 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-7 and 10-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 10-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/19/2008 has been entered. Claims 1-7 and 10-17 are pending and an action on the merits is as follows.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 2, 4-7 and 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lipkover (US 5,421,816)** in view of **Shimada et al. (US 5,267,985), Kost et al. (US 4,767,402),** and **Hidaka (US 4,990,340).**

**Regarding claims 1 and 7,** Lipkover discloses an ultrasonic percutaneous (transdermal) penetration device, comprising: a medicine (pharmaceutical agent) containing an active ingredient (column 4, lines 55-56), an irradiation (stimuli transducer) unit that applies ultrasonic waves (column 4, lines 62-64) having a frequency of not less than 0.5 MHz (column 5, lines 24-26) to skin (column 4, lines 65-67); and a control unit (column 4, lines 67-68; column 5, lines 1-2) that controls irradiation conditions of the irradiation unit, but fails to disclose a second transducer generating waves at a second frequency and the control unit controlling the first and second transducers, a frequency of 3 MHz to 7MHz, and the active ingredient being selected from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract.

Shimada et al. teaches a second transducer that produces a separate frequency from the first transducer and a control unit (voltage source) that controls the transducers (column 5, lines 46-53), but fails to disclose the frequency range of 3-7 MHz and the specific active ingredient.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a second transducer at a different frequency to enhance the delivery of a substance into an area (Shimada; column 3, lines 31-42).

Kost et al. teaches a transdermal drug delivery device with ultrasonic enhancement that operates in the range of 20 kHz (.02 MHz) and 10 MHz (column 4, lines 28-31), but not the specific active ingredient.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the range between 3 and 7 MHz, to enhance the transdermal transfer of molecules (Kost et al.; column 4, lines 28-31).

Hidaka et al. teaches a transdermal (percutaneous) drug delivery device containing the medicine (drug) glutathione (column 6, lines 62-63; column 9, line 28).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use glutathione as the medicine as it has been proven to have the ability to transdermally transfer the medicine to the patient (Hidaka et al.; column 10, lines 17-20), and the use of an ultrasonic device would only increase the absorption of the drug.

**Regarding claim 2,** Lipkover discloses the control unit controlling the frequency, period between on and off of power and irradiation time (column 5, lines 22-27), which are irradiation conditions of ultrasonic waves.

**Regarding claim 4,** Lipkover discloses wherein the irradiation unit applies not less than two ultrasonic waves (stimulus wave, 5KHz-1MHz and pumping pulses, 50 MHz-300MHz) having different frequencies (column 5, lines 23-32).

**Regarding claim 5,** Lipkover discloses the irradiation unit applies an ultrasonic wave having a frequency of virtually 1 MHz (column 5, lines 24-25) and an ultrasonic wave having a frequency of not less than 2 MHz (column 5, lines 30-32).

**Regarding claim 6,** Lipkover discloses a device further comprising a thermal tool (infrared emitter) for warming a portion to be subjected to penetration of the medicine and a photo stimulator (laser emitter) that applies photic stimulation to the portion to be subjected to penetration of the medicine (column 5, lines 40-48).

**Regarding claim 10,** Lipkover, Shimada, Kost et al. and Hidaka et al. disclose the invention substantially as stated above, with Hikdaka et al. teaching the active ingredient being selected from the group consisting of vitamin A, vitamin A acid derivatives, retinol, glutathione, α-hydroxy acid and a cell activation agent.

Hidaka et al. teaches a transdermal (percutaneous) drug delivery device containing the medicine (drug) vitamin A (column 6, lines 62-63; column 9, line 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use vitamin A as the medicine as it has been proven to have the ability to transdermally transfer the medicine to the patient (column 10, lines 17-20), and the use of an ultrasonic device would only increase the absorption of the drug.

**Regarding claim 11,** Lipkover, Shimada, Kost et al. and Hidaka et al. disclose the invention substantially as stated above, with Hikdaka et al. teaching the active ingredient being selected from the group consisting of vitamin B group, capsaicin and caffeine.

Hidaka et al. teaches a transdermal (percutaneous) drug delivery device containing the medicine (drug) capsaicin (column 6, lines 62-63; column 7, line 31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use capsaicin as the medicine as it has been proven to have the

ability to transdermally transfer the medicine to the patient (column 10, lines 17-20), and the use of an ultrasonic device would only increase the absorption of the drug.

**Regarding claim 12** Lipkover, Shimada, Kost et al. and Hidaka et al. disclose the invention substantially as stated above, with Hikdaka et al. teaching the active ingredient being selected from the group consisting of a thiocarbamate-based agent, an imidazole-based agent, an allylamine-based agent, an amorolfine-based agent, an undecylenic acid and derivatives thereof, an antifungal agent and an antitrichophyton agent.

Hidaka et al. teaches a transdermal (percutaneous) drug delivery device containing the medicine (drug) an antifungal agent (column 6, lines 62-63; column 8, line 35).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an antifungal agent as the medicine as it has been proven to have the ability to transdermally transfer the medicine to the patient (column 10, lines 17-20), and the use of an ultrasonic device would only increase the absorption of the drug.

**Regarding claim 13,** Lipkover discloses the medicine is impregnated into a base material (column 4, lines 58-60).

**Regarding claim 14,** the combination of Lipkover, Shimada, Kost et al. and Hidaka et al. as set forth above discloses the method comprising the step of simultaneously as a medicine containing an active ingredient is made in contact with the skin, applying ultrasonic waves having a frequency of not less than 0.5 MHz to a skin

surface through the medicine (Lipkover; column 9, lines 47-55), and a second transducer generating waves at a second frequency and the control unit controlling the first and second transducers, a frequency between 3 and 7 MHz and an active ingredient being selected from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract.

**Regarding claim 15,** the combination of Lipkover, Shimada, Kost et al. and Hidaka et al. as set forth above discloses the method comprising the step of after a medicine containing an active ingredient has been made in contact with the skin, applying ultrasonic waves having a frequency of not less than 0.5 MHz to a skin surface through a medium that transmits ultrasonic waves (Lipkover; column 6, lines 27-33), a frequency between 3 and 7 MHz and an active ingredient being selected from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract.

Lipkover discloses the first ultrasonic waves stimulating the skin, then the medicine being applied, and then pulses of ultrasonic waves being applied that "pump" the medicine through the skin, which is a medium that transmits ultrasonic waves.

**Regarding claim 16,** the combination of Lipkover, Shimada, Kost et al. and Hidaka et al. as set forth above discloses the method comprising the step of after having applied ultrasonic waves having a frequency of not less than 0.5 MHz to a skin surface, a medicine containing an active ingredient is made in contact with the skin to which the ultrasonic waves have penetrated (Lipkover; column 6, lines 27-33), and a

second transducer generating waves at a second frequency and the control unit controlling the first and second transducers. a frequency between 3 and 7 MHz and an active ingredient being selected from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract.

**Regarding claim 17**, the combination Lipkover, Shimada, Kost et al. and Hidaka et al. as set forth above discloses the method comprising the steps of the following two processes: a process in which ultrasonic waves having a frequency of not less than 0.5 MHz are applied to the skin surface (Lipkover; column 6, lines 27-33); and a process in which, simultaneously as the medicine containing an active ingredient is made in contact with the skin, ultrasonic waves having a frequency of not less than 0.5 MHz are applied to the skin surface through the medicine (Lipkover; column 9, lines 47-55), and carrying out the selected processes time-serially in succession, and a second transducer generating waves at a second frequency and the control unit controlling the first and second transducers, with a frequency between 3 and 7 MHz and an active ingredient being selected from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract.

4. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Lipkover (US 5,421,816)** in view of **Shimada et al. (US 5,267,985), Kost et al. (US 4,767,402),** and **Hidaka (US 4,990,340)** as applied to claim 1 above, and further in view of **Rowe et al. (US 6,234,990 B1).**

**Regarding claim 3** Lipkover, Shimada, Kost et al. and Hidaka et al. disclose the invention substantially as stated above, but fail to disclose a detection unit that detects the depth of a portion for penetration of the medicine, wherein the control unit controls the irradiation conditions so as to allow the medicine to penetrate to the depth detected by the detection unit.

However, Rowe et al. teaches a detection unit (sensor) that detects the depth of a portion for penetration of the medicine, wherein the control unit (controller, 90) controls the irradiation conditions so as to allow the medicine to penetrate to the depth detected by the detection unit (column 12, lines 1-5 and 9-16).

It would have been obvious to one having ordinary skill in the art at the time in the invention was made to provide a depth sensor on the device to allow the medicine to penetrate to the correct depth (column 12, lines 10-12).

***Response to Arguments***

5. Applicant's arguments filed 12/19/2008 have been fully considered but they are not persuasive.

The disclosure by Kost et al. describes a device to enhance the transdermal delivery of a drug using ultrasonic waves. The disclosed range (20 kHz to 10MHZ) encompasses the applicant's claimed range, and selecting a specific frequency would have been obvious to one having ordinary skill in the art at the time the invention was made since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

6. In response to applicant's argument that the active ingredient disclosed by Hidaka does not achieve a desired whitening or wrinkle reduction effect, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The ingredient was disclosed by Hidaka and would perform the same function as the claimed ingredient.

7. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie A Szpira/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731